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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,795	01/13/2004	Samuel D. Prien	13241US03	1541

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EXAMINER	
BEISNER, WILLIAM H	
ART UNIT	PAPER NUMBER
1744	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/756,795	PRIEN, SAMUEL D.	
	Examiner	Art Unit	
	William H. Beisner	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-7 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-7 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 13 January 2004 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 11/04;10/06.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. It is noted that this application appears to claim subject matter disclosed in prior Application No. PCT/US02/28970, filed 9/12/2002. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e), 120, 121, or 365(c). See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, 121, or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an

unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Information Disclosure Statement

2. The information disclosure statements filed 11/22/04 and 10/10/2006 have been considered and made of record.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 4 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by AKIO (JP 06-305901).

With respect to claim 1, the reference of AKIO discloses an apparatus (See Figure 1) that includes a perfusion loop that includes an organ container (9), a bubble remover (8) and an oxygenator (6). With respect to the claimed free radical scavenger, the reference discloses that the perfusion media includes adenosine (See the English language Abstract and paragraph [0021] of the English language machine translation.

With respect to the perfusion fluid of claims 4 and 5, the reference discloses that the perfusion media includes adenosine (See the English language Abstract and paragraph [0021] of the English language machine translation.

5. Claim 4 is rejected under 35 U.S.C. 102(b) as being anticipated by Polyak et al.(US 2002/0115634).

With respect to claim 4, the reference of Polyak et al. discloses a perfusion fluid that includes a free radical scavenger in a amount effective to increase the length of the period which an ex vivo organ will remain viable in the perfusion fluid (See paragraph [0016]).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Polyak et al.(US 2002/0115634) in view of Rath et al.(US 5,230,996).

The reference of Polyak et al. has been discussed above.

While the reference of Polyak et al. discloses a preservation solution that includes an oxygen radical scavenger, claim 2 6 differs by reciting that the composition is provided in time-release form.

The reference of Rath et al. discloses that when exposing a tissue to a desired treatment composition, it is known in the art to provide the treatment composition in time-release form to achieve constant fluid concentrations of the composition over time (See column 6, lines 23-27).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the scavenger of the primary reference in time-release form for the known and expected benefit suggested by the reference of Rath et al.

9. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Polyak et al.(US 2002/0115634) in view of Rath et al.(US 5,230,996) taken further in view of Chien et al.(US 3,992,518).

The combination of the references of Polyak et al. and Rath et al. has been discussed above.

Claim 7 differs by reciting that the time-release composition includes a body of organosiloxane material.

The reference of Chien et al. discloses that the use of organosiloxane material is conventional in the art as a time-release carrier material (See Example 1).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ an organosiloxane material as a carrier for the composition of the modified primary reference for the known and expected result of providing an art recognized means for providing the time-release feature suggested by the reference of Rath et al.

10. Claims 2 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over AKIO (JP 06-305901) in view of Rath et al.(US 5,230,996).

The reference of AKIO (JP 06-305901) has been discussed above.

While the reference of AKIO discloses a preservation solution that includes adenosine, claims 2 and 6 differ by reciting that the composition is provided in time-release form.

The reference of Rath et al. discloses that when exposing a tissue to a desired treatment composition, it is known in the art to provide the treatment composition in time-release form to achieve constant fluid concentrations of the composition over time (See column 6, lines 23-27).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the scavenger of the primary reference in time-release form for the known and expected benefit suggested by the reference of Rath et al.

11. Claims 3 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over AKIO (JP 06-305901) in view of Rath et al.(US 5,230,996) taken further in view of Chien et al.(US 3,992,518).

The combination of the references of AKIO (JP 06-305901) and Rath et al. has been discussed above.

Claims 3 and 7 differ by reciting that the time-release composition includes a body of organosiloxane material.

The reference of Chien et al. discloses that the use of organosiloxane material is conventional in the art as a time-release carrier material (See Example 1).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ an organosiloxane material as a carrier for the composition of the modified primary reference for the known and expected result of providing an

art recognized means for providing the time-release feature suggested by the reference of Rath et al.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The reference of Dobson (US 6,955,814) is cited as prior art which recognizes adenosine as a free radical scavenger.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys J. Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

William H. Beisner
Primary Examiner
Art Unit 1744

WHB